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ORIGINAL ARTICLE

One-year weight losses in the Tianjin Gestational Diabetes Mellitus Prevention Programme: A randomized clinical trial

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Aims: To report the weight loss findings after the first year of a lifestyle intervention trial among women with gestational diabetes mellitus (GDM).

Methods: A total of 1180 women with GDM were randomly assigned (1:1) to receive a 4-year lifestyle intervention (intervention group, *n* = 586) or standard care (control group, *n* = 594) between August 2009 and July 2011. Major elements of the intervention included 6 face-to-face sessions with study dieticians and two telephone calls in the first year, and two individual sessions and two telephone calls in each subsequent year.

Results: Among 79% of participants who completed the year 1 trial, mean weight loss was 0.82 kg (1.12% of initial weight) in the intervention group and 0.09 kg (0.03% of initial weight) in the control group (*P* = .001). In a prespecified subgroup analysis of people who completed the trial, weight loss was more pronounced in women who were overweight (body mass index ≥24 kg/m^2) at baseline: mean weight loss 2.01 kg (2.87% of initial weight) in the intervention group and 0.44 kg (0.52% of initial weight) in the control group (*P* < .001). Compared with those in the control group, women in the intervention group had a greater decrease in waist circumference (1.76 cm vs 0.73 cm; *P* = .003) and body fat (0.50% vs 0.05% increase; *P* = .001).

Conclusion: The 1-year lifestyle intervention led to significant weight losses after delivery in women who had GDM, and the effect was more pronounced in women who were overweight at baseline.

KEYWORDS

gestational diabetes, randomized clinical trials, weight loss

1 | INTRODUCTION

Gestational diabetes mellitus (GDM) is increasingly common around the world.[1–3] In China, the prevalence of GDM increased from 2.4% in 1999 to 8.1% in 2012,[4,5] with similar levels now to those in the United States (~7%) and Europe (~6%).[1,2] Among women diagnosed with GDM, ~30% to 50% will develop type 2 diabetes within 5 years of the index pregnancy.[6,7] Women with GDM usually have a higher body weight before pregnancy, during pregnancy and after delivery compared with women without GDM.[5,8,9] Meanwhile, overweight and obesity are associated with an increased risk of diabetes. A recent meta-analysis has shown that a 1-unit increase in body mass index (BMI) increases the risk of diabetes by 18%.[10]

Several recent randomized clinical trials (RCTs) have shown that a lifestyle intervention can prevent or delay type 2 diabetes risk in overweight/obese adults with impaired glucose tolerance.[11–13] These RCTs generally have several intervention goals, with weight loss chosen as the primary intervention goal. Thus far, very few ongoing or planned RCTs have tested whether a postpartum lifestyle intervention during the early postpartum period can prevent or delay type 2 diabetes risk among women with GDM. The Tianjin Gestational Diabetes Mellitus Prevention Programme aims to investigate the extent to which a postpartum lifestyle intervention, given soon after delivery, can reduce the risk or delay the onset of type 2 diabetes in women with GDM. The aim of the present study was to present weight loss results after the first year of the intervention in the Tianjin Gestational Diabetes Mellitus Prevention Programme.

2 | PARTICIPANTS AND METHODS

2.1 | Study design and participants

The Tianjin Gestational Diabetes Mellitus Prevention Program is a 2-aim, 4-year RCT being carried out at the Tianjin Women's and Children's Health Centre, Tianjin, China.[14] The study design, including recruitment, screening visits, inclusion and exclusion criteria, has been described in detail elsewhere.[14–18] We recruited women (aged >24 years) with GDM diagnosed on the basis of the World Health Organization (WHO) criteria[19] from 6 urban districts in Tianjin between July 1, 2005 and June 30, 2009. All pregnant women who were at 26 to 30 gestational weeks participated in a 1-hour oral glucose tolerance test (OGTT) with 50-g glucose load. Women who had a glucose reading ≥7.8 mmol/L were invited to undergo a 2-hour OGTT with a 75-g glucose load at the Tianjin Women's and Children's Health Centre. Women with a 75-g glucose 2-hour OGTT result confirming either diabetes (fasting glucose ≥7 mmol/L or 2-hour glucose ≥11.1 mmol/L) or impaired glucose tolerance (2-hour glucose ≥7.8 mmol/L and <11.1 mmol/L) using the WHO criteria were regarded as having GDM.[4] After participants completed the baseline survey administered by health workers from the study centre between August 1, 2009 and July 31, 2011, 1180 eligible women with GDM were randomized to either a 4-year lifestyle intervention (n = 586) or a control group (n = 594).[14] Ethics approval was granted by the Human Subjects Committee of the Tianjin Women's and Children's Health Centre, and all participants provided written informed consent. This trial is registered with ClinicalTrials.gov, number NCT01554358, and is ongoing.

The inclusion criteria for the women were: age 20 to 49 years at baseline survey and presence of GDM between 2005 and 2009. The exclusion criteria were: age <20 or ≥50 years; fasting glucose ≥7.0 mmol/L or 2-hour glucose ≥11.1 mmol/L in the OGTT at the screening visit; taking medication known to alter OGTTs; presence of any chronic diseases that could seriously reduce life expectancy or ability to participate in the study; inability or unwillingness to give informed consent or communicate with study staff; and current pregnancy, or planning to become pregnant in the next 2 years.[14]

2.2 | Run-in

Before randomization, eligible participants received two classes on general principles of lifestyle intervention for the prevention of type 2 diabetes and obesity. Participants discussed previous experience with lifestyle changes and obstacles encountered. Accumulating evidence showing that lifestyle intervention is effective for the prevention of type 2 diabetes was presented. The specific lifestyle intervention programme began after randomization.

2.3 | Randomization and masking

Participants were randomized after the project physician and project director had determined that they: demonstrated satisfactory interest in joining a lifestyle intervention during the run-in; expressed willingness to continue in the trial regardless of the group to which they might be randomly allocated; met all inclusion/exclusion criteria; and provided all baseline data. The Statistical Package for Social Sciences was used to generate a list of 1200 random allocation statuses, and the list of random assignments was kept centrally by an independent person. After exclusion, 1180 eligible women with GDM were randomly assigned (1:1) to receive a 4-year lifestyle intervention (intervention group) or standard care (control group; Figure S1). Because of the nature of the intervention, the participants and study coordinator could not be blinded to the study group assignment; however, the team members involved in assessing outcomes of the participants and data analysts were blinded to group assignment.

2.4 | Lifestyle intervention

The intervention methods have been described in a previous report.[14] The present description is limited to the first year of the trial. Major elements of the intervention included 6 face-to-face sessions with study dieticians and two telephone calls in the first year.

2.4.1 | Intervention group

The first year of the intervention was a weight loss phase, which included the first 4 weeks dietary intervention. In the first week, each participant met one-on-one with a dietician who instructed the participant on how to achieve the 5 goals of the intervention: (1) reduction of 5% to 10% of initial body weight in women with BMI ≥24 kg/m^2 by reducing at least 10% of total calories in their normal meals,

and no weight loss for participants with GDM with a BMI <24 kg/m^2, using the Chinese BMI classification standard[20]; (2) total fat intake <30% of energy consumed; (3) carbohydrate intake 55% to 65% of energy consumed; (4) fibre intake 20 to 30 g per day; and (5) moderate or vigorous exercise for at least 30 minutes daily, 7 days each week. Based on each participant's current status of body weight, breastfeeding, physical activity, along with food and nutrient intakes, which had been assessed at the baseline survey examination, the dietician gave participants advice on how to modify their diet, which included: intake of appropriate energy; inclusion of appropriate amounts of fish, eggs, low-fat milk, lean meat and reduction in fatty meats and animal fat in the diet; avoidance/reduction of simple sugars and refined carbohydrates; and inclusion of more fibre-rich food, such as whole grains, wheat flour with standard grade, corn/corn starch, brown rice, vegetables and fruits. To help participants meet these healthy diet goals, the dietician provided the participants with a suggested daily menu for 5 days. Taking into consideration individual food preferences, the dietician established with the participants a minimum of 5 breakfasts, 5 lunches and 5 dinners that they ate within the 5-day cycle menu. Moreover, the dietician taught each participant to self-select a diet that matched her specific diet prescription for macronutrients and energy, and also introduced a method to exchange foods as depicted in a handbook. This dietary intervention followed in week 4.

The physical activity goal was to gradually increase physical activity from 15 to 30 minutes per day during the first 4 weeks of the physical activity intervention. Participants had been instructed to engage in moderate or vigorous physical activity during commuting (walking or cycling to/from work) or leisure time (eg, walking, cycling) for at least 15 minutes per day, 7 days per week during week 1. The level of physical activity increased to at least 30 minutes per day, 7 days per week in week 4, and was maintained at that level during the entire trial period.

Diet and physical activity monitoring took place from week 4 to month 12. Each participant completed a questionnaire on changes in major dietary habits and physical activity habits from the last visit, and 3-day 24-hour food records 5 times during the first year for assessment by the dietician. The dietician reviewed questionnaires and food records, calculated the nutrient intakes using the dietary analysis software developed by China CDC, provided an assessment about deviations from the suggested diets and exercises, and then offered specific suggestions at each visit. Body weight was measured at each visit to monitor compliance.

The participants received 2 telephone calls to encourage continued compliance with the intervention in the first year. The dietician adjusted treatment advice to improve dietary adherence to weight goals. Almost 100% of mothers had a mobile phone.

2.4.2 | Usual care group

Before randomization the women in the usual care group were educated regarding the general principles of healthy lifestyle that can aid type 2 diabetes and obesity prevention, and were also informed about the current evidence showing that the lifestyle intervention is effective in women at high risk of type 2 diabetes. They were given general oral and written information about awareness of diabetes, dietary modification and physical activity increase at subsequent annual visits, but no specific individualized programmes were offered. They completed a questionnaire on changes in major dietary and exercise habits, 3-day 24-hour food records and questionnaires at baseline and at the first year annual visit. The completeness of the food records was checked at the face-to-face session with a dietician at each visit.

2.5 | Measurement

All study participants filled in a questionnaire on their sociodemographic characteristics (age, marital status, education, income and occupation), history of GDM (values of fasting and 2-hour glucose in the OGTT and treatment of GDM during the pregnancy), family history (diabetes, coronary heart disease, stroke, cancer and hypertension), medical history (hypertension, diabetes, and hypercholesterolaemia), pregnancy outcomes (pre-pregnancy weight, weight gain in pregnancy and number of children), postpartum weight and fasting glucose status, dietary habits (a self-administered food frequency questionnaire to measure the frequency and quantity of intake of 33 major food groups and beverages during the past year),[21] alcohol intake, smoking habits, physical activity (the frequency and duration of 5 domains of physical activity including occupational, commuting [walking or cycling to/from work], leisure time [11 recreational activities], household [cooking, washing clothes, cleaning, and looking after children] and sedentary activities),[22,23] and sleep status (duration of usual sleep and night shift work) at the baseline survey.

Changes in lifestyle were measured using a questionnaire on changes in major dietary and physical activity habits from the last visit, a 3-day 24-hour food record was completed at each clinical visit by women in the intervention group, and a 3-day 24-hour food record and a self-administered questionnaire was completed at the first year annual visit. The performance of 3-day 24-hour food records,[21] the food frequency questionnaire,[21] and the questionnaire assessing physical activity[22,23] were validated in the China National Nutrition and Health Survey in 2002.

Body weight, height, waist and hip circumferences, body fat (measured using Tanita Body Composition Analyzers SC-240), blood pressure, and heart rate were measured in all women using the standardized protocol at the baseline and first year annual visits. Body weight was measured at each clinical visit in women in the intervention group.

2.6 | Statistical analysis

The primary outcome of the present analyses was the change in body weight or percentage reduction in initial weight from baseline to year 1. The secondary outcomes included changes in waist circumference, body fat, energy intake and leisure-time physical activity from baseline to year 1. We also assessed changes in body weight, energy intake, leisure time physical activity from baseline to months 1, 3, 6 and 9 among women in the intervention group. A 2-tailed paired *t* test if normal distribution was not rejected, or Mann–Whitney *U* test otherwise, was used to analyse the differences in continuous measures while the χ^2 test was used to compare the differences in

categorical measures between the two groups at baseline and at year 1. A P value <.05 was considered statistically significant. Statistical analyses were performed with IBM SPSS Statistics 23.0 (IBM SPSS, Chicago, IL, USA).

We performed an intention-to-treat analysis in which long-term weight loss for people who withdrew early from the study (after at least 3 months of participation) was imputed on the basis of a rate of 0.3 kg per month of regained weight after withdrawal.[24] Weight regain was estimated from time of dropout up to 3, 6, 9 or 12 months according to this rate, however, regain was truncated at no change from baseline whenever the extrapolation would lead to a positive weight gain. When an individual's weight at dropout represented a gain in weight relative to baseline, no additional gain was imputed, but the unfavourable gain was simply carried forward to 3, 6, 9 or 12 months as needed. Zero weight change was assumed for 10 participants who did not return after 3 months and all participants in the control group who did not attend the year 1 visit. Waist circumference and body fat were also analysed according to the intention-to-treat principle, with zero change from baseline imputed for missing data.

3 | RESULTS

Between August 1, 2009, and July 31, 2011, we recruited and randomly assigned 1180 women into the intervention group (n = 586) or the control group (n = 594; Figure S1). Of these women, 930 (79%) completed the year 1 study visit. The completion rates were 78.5% in the intervention group and 79.1% in the control group (P = .83). Baseline characteristics were similar among all participants assigned to the intervention or the control group, and among participants assigned to the intervention or the control group who completed the year 1 study, as well as between all participants and those who completed the year 1 study (Tables 1 and Table S1).

At the end of year 1, mean weight loss among all participants was 0.64 kg (0.86% of initial weight) in the intervention group and 0.07 kg (0.02% of initial weight; P = .002; P = .003) in the control group (Figure 1A,C). Among 79% of participants who completed the year 1 study, mean weight loss was 0.82 kg (1.12% of initial weight) in the intervention group and 0.09 kg (0.03% of initial weight; P = .001; P = .002) in the control group (Table 2 and Figure 1B,D). Compared with women in the control group, women in the intervention group had a greater decrease in waist circumference (1.39 cm vs 0.58 cm in all participants, P = .004; 1.76 cm vs 0.73 cm among those who completed the year 1 study, P = .003 [Table 2 and Figure 1E,F]) and body fat (0.39% vs 0.04% increase in all participants, P = .001; 0.50% vs 0.05% increase among those who completed the year 1 study, P = .001 [Table 2 and Figure 1G,H]). Women in the intervention group were also more likely to achieve the goals of intervention compared with those in the control group: weight reduction goal among overweight women at baseline 30.2% vs 17.5%, P = .003; exercise goal among all participants: 22.4% vs 14.3%, P = .001, respectively (Table 2).

In a prespecified subgroup analysis, weight loss was more pronounced in women who were overweight (BMI ≥24 kg/m^2) at baseline and completed the year 1 study: mean weight loss was 2.01 kg (2.87% of initial weight) in the intervention group and 0.44 kg (0.52% of initial weight; P < .001) in the control group (Table 2 and Figure 1B,D). Women in the intervention group who were overweight at baseline were more likely to decrease their waist circumference and body fat compared with overweight women in the control group (P < .001; Figure 1E–H).

Table 3 and Figure 2 present changes in body weight, energy intake and leisure time physical activity from baseline to months 1, 3, 6 and 9 among participants in the intervention group. Participants who completed interventions at one of the visits at months 1, 3, 6 and 9 lost a mean of 0.41 kg weight at month 1, 0.68 kg at month 3, 0.74 kg at month 6 and 1.00 kg at month 9. Participants in the intervention group reduced daily energy intake by up to 89 kcal and increased daily leisure time physical activity by up to 2.3 minutes from baseline to months 1 to 9. Women who were overweight at baseline were more likely to lose weight, reduce daily energy intake and increase daily leisure time physical activity within the first year compared with women with normal weight at baseline.

4 | DISCUSSION

The principal finding of the present study was that the 1-year lifestyle intervention shortly after delivery led to a significant weight loss in women who had recent history of GDM, and the effect was more pronounced in those who were overweight after delivery. Lifestyle intervention also decreased waist circumference and body fat among the women.

The available data from several RCTs, such as the Da Qing Diabetes Prevention Study,[11] the Finnish Diabetes Prevention Study,[12] and the Diabetes Prevention Program[13] have demonstrated that effective lifestyle intervention strategies can prevent or delay the progression to type 2 diabetes among overweight or obese adults with impaired glucose tolerance. A weight reduction of at least 5% to 7% of initial body weight through reducing energy intake, a healthy diet and increasing physical activity were chosen as the principal intervention goal among overweight or obese participants in these RCTs.[12,13]

Approximately 6% to 14% of pregnancies worldwide are affected by GDM.[1–5] Women with GDM are 7 times more likely to develop type 2 diabetes than those without GDM.[6,7] Women with GDM usually have a higher body weight before pregnancy, during pregnancy and after delivery, and higher postpartum weight retention compared with women without GDM.[5,8,9] To our knowledge, no successfully completed RCTs have examined whether lifestyle intervention during the early postpartum period can prevent or delay type 2 diabetes risk among women with a history of GDM. To date, only a very few RCTs, with small sample sizes or a short intervention period, have tested whether a lifestyle intervention could improve postpartum weight retention among women with GDM after early delivery. One study in 75 women with GDM indicated that a web-based lifestyle modification programme for women with recent GDM decreased postpartum weight retention from 6 weeks to 12 months postpartum.[25] The Gestational Diabetes' Effects on Moms RCT found that a Diabetes Prevention Program-derived telephone-based lifestyle intervention

TABLE 1 Baseline characteristics of women with gestational diabetes mellitus

	All participants		P	Participants who completed the Year 1 study		P
	Intervention group	Control group		Intervention group	Control group	
Number of participants	586	594		460	470	
Age, years	32.3 (3.4)	32.4 (3.6)	.58	32.5 (3.4)	32.5 (3.6)	.90
Time from delivery to baseline, months	27.2 (10.4)	27.1 (10.3)	.82	26.9 (10.5)	27.0 (10.3)	.84
Time from delivery to the end of year 1, months	-	-		42.5 (12.0)	42.2 (11.8)	.68
Height, cm	160 (5.6)	160 (5.1)	.70	160 (5.6)	160 (5.1)	.70
Body weight, kg	61.3 (10.4)	61.8 (10.6)	.46	60.9 (10.1)	61.9 (10.2)	.13
BMI, kg/m^2	23.8 (3.7)	24.0 (3.9)	.33	23.7 (3.6)	24.0 (3.9)	.06
BMI category, %[a]			.71			.25
<24 kg/m^2	57.3	55.2		58.9	53.8	
2 to 27.9 kg/m^2	28.7	30.8		28.7	31.1	
≥28 kg/m^2	14.0	14.0		12.4	15.1	
Waist circumference, cm	79.8 (9.1)	80.3 (9.3)	.41	79.4 (8.9)	80.3 (9.3)	.16
Body fat, %	32.6 (5.6)	32.9 (5.8)	.41	32.4 (5.6)	32.9 (5.8)	.11
Education, %			.025			.016
<13 y	23.4	19.9		22.8	19.8	
13 to 16 y	67.4	74.1		67.4	74.7	
≥16 y	9.2	6.1		9.8	5.5	
Family income			.84			.82
<5000 yuan/mo	25.9	27.1		26.7	28.5	
5000 to 8000 yuan/mo	37.7	36.2		36.3	36.0	
≥8000 yuan/mo	36.3	36.7		37.0	35.5	
Family history of diabetes, %	34.5	33.7	.77	34.6	33.8	.81
Current smoking, %	1.5	2.4	.56	1.3	1.9	.63
Passive smoking, %	51.7	54.9	.27	51.3	55.5	.20
Current alcohol drinkers, %	22.2	20.9	.58	22.2	19.8	.37
Occupational physical activity, %			.27			.10
Light	26.1	25.6		25.7	26.4	
Moderate	57.0	53.9		58.7	53.0	
Vigorous	16.9	20.5		15.7	20.6	
Walking or cycling to and from work, %			.036			.08
0 min/d	75.1	81.1		75.9	81.7	
1 to 29 min/d	5.3	4.5		5.0	3.2	
≥30 min/d	19.6	14.3		19.1	15.1	
Leisure time physical activity, %			.81			.47
0 min/d	78.5	79.0		77.8	81.1	
1 to 29 min/d	19.1	19.2		19.8	17.0	
≥30 min/d	2.4	1.9		2.4	1.9	
Sitting time at home, h/d	3.2 (2.2)	3.2 (2.0)	.51	3.1 (2.2)	3.2 (1.9)	.34
Sleep time, h/d	7.9 (1.1)	7.8 (1.0)	.13	7.8 (1.0)	7.7 (1.1)	.24
Dietary intakes[b]						
Energy, kcal/d	1685 (415)	1697 (469)	.65	1705 (408)	1701 (465)	.89
Protein, % of energy	16.9 (2.7)	17.1 (2.9)	.25	16.2 (2.5)	16.4 (2.7)	.11
Fat, % of energy	33.5 (6.3)	33.5 (6.4)	.89	33.7 (6.3)	33.6 (6.2)	.64
Carbohydrate, % of energy	49.6 (7.1)	49.4 (7.5)	.63	50.1 (6.9)	50.0(7.2)	.86
Fibre, g/1000 kcal	6.2 (1.9)	6.2 (2.0)	.41	6.2 (1.8)	6.3 (2.1)	.81
Vegetable intake, g/d	258 (119)	256 (127)	.84	261 (116)	257 (125)	.62
Fruit intake, g/d	126 (131)	121 (115)	.48	123 (122)	123 (118)	.99

Abbreviation: BMI, body mass index. Data are mean (SD), and percentage (%) unless otherwise indicated.

[a] According to the Chinese standard, BMI is classified as normal (BMI <24 kg/m^2), overweight (BMI 24-27.9 kg/m^2), and obese (BMI ≥28 kg/m^2).

[b] Dietary intakes are assessed by 3-d 24-h food records.

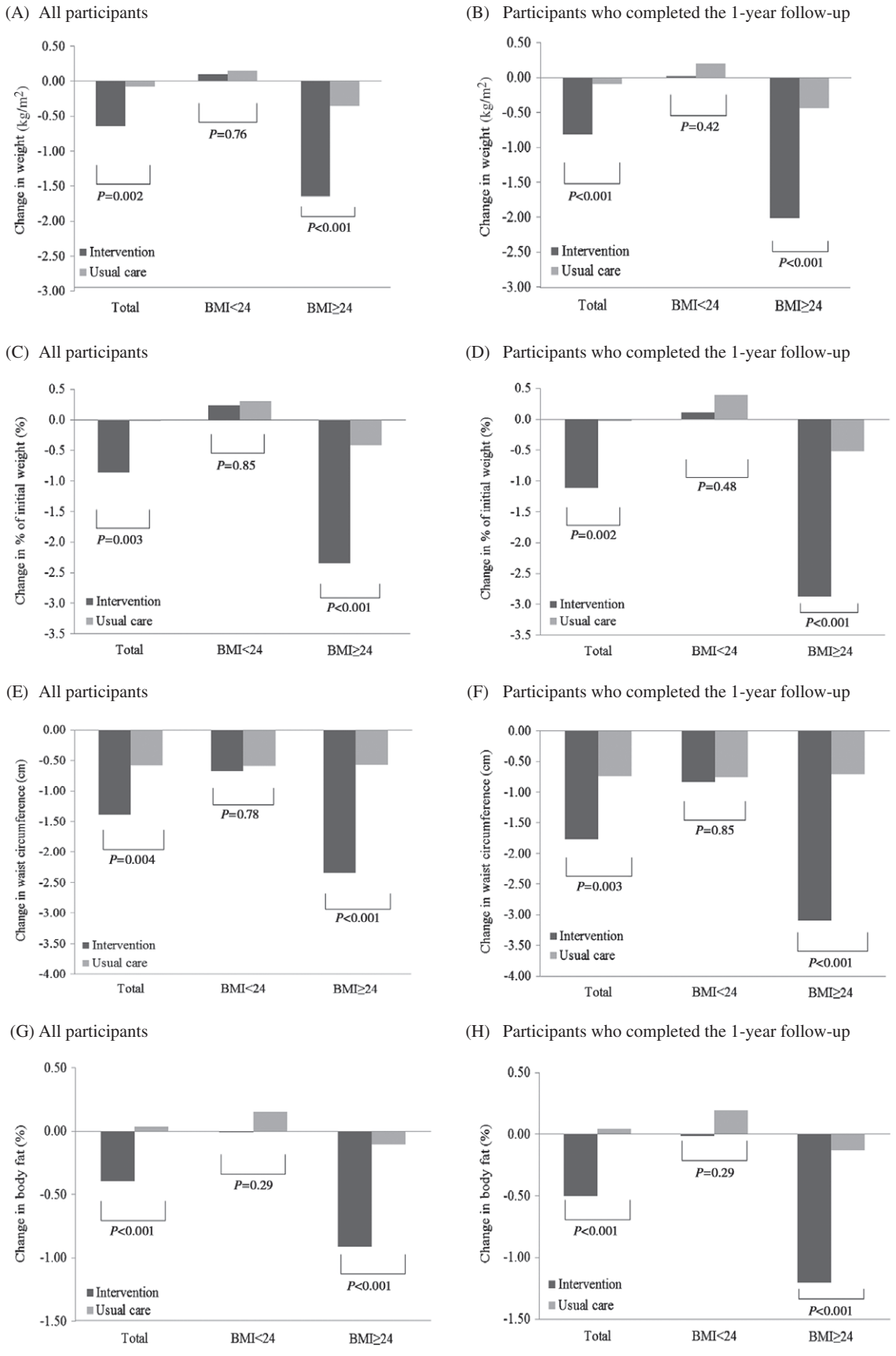

FIGURE 1 Changes in body weight, percentage reduction of initial weight, waist circumference and body fat from baseline to year 1 in the participants in the intervention and control groups. Panels A, C, E and G show the change in body weight, the change in percentage reduction of initial weight, the change in waist circumference, and the change in body fat, respectively, for all participants (a total of 1180 women); missing data were imputed. Panels B, D, F and H show the change in body weight, the change in percentage reduction of initial weight, the change in waist circumference, and the change in body fat, respectively, for participants who completed the year 1 visit (a total of 930 women)

TABLE 2 Changes in body weight, waist circumference, and major lifestyle factors from baseline to the end of year 1 among participants who completed the year 1 study

	Intervention group	Control group	P
Overall participants			
N	460	470	
Change in weight			
kg	−0.82 (3.52)	−0.09 (3.29)	.001
Percent reduction in initial weight	−1.12 (5.43)	−0.03 (4.99)	.002
Change in BMI, kg/m^2	−0.32 (1.38)	−0.04 (1.27)	.001
Change in waist circumference, cm	−1.76 (5.40)	−0.73 (5.18)	.003
Change in body fat, %	−0.50 (2.59)	0.05 (2.19)	.001
Change in energy intake, kcal/d[a]	5.81 (490)	2.66 (525)	.095
Change in leisure time activity, min/d	1.76 (9.73)	0.36 (11.9)	.048
Interventional goals, %			
Weight reduction >5% in initial weight	19.3	13.2	.011
Fat intake <30% of energy intake[a]	41.7	40.2	.64
Carbohydrate intake >55% of energy intake[a]	50.2	51.9	.60
Fibre intake >20 g/d[a]	5.0	2.1	.018
Exercise >30 min/d (commute and leisure)	22.4	14.3	.001
Participants with baseline BMI <24 kg/m^2			
N	271	253	
Change in weight			
kg	0.02 (2.52)	0.20 (2.51)	.42
Percent reduction in initial weight	0.11 (4.53)	0.39 (4.51)	.48
Change in BMI, kg/m^2	0.01 (0.98)	0.07 (0.96)	.42
Change in waist circumference, cm	−0.84 (4.72)	−0.76 (4.57)	.85
Change in body fat, %	−0.01 (2.34)	0.20 (2.16)	.28
Change in energy intakes, kcal/d[a]	63.5 (463)	0.12 (493)	.13
Change in leisure time activity, min/d	1.34 (9.68)	−0.29 (11.7)	.083
Interventional goals, %			
Weight reduction >5% in initial weight	11.8	9.5	.39
Fat intake <30% of energy intake[a]	44.6	41.9	.52
Carbohydrate intake >55% of energy intake[a]	53.9	53.8	.97
Fibre intake >20 g/d[a]	5.5	2.4	.065
Exercise >30 min/d (commute and leisure)	26.6	13.0	<.001
Participants with baseline BMI ≥24 kg/m^2			
N	189	217	
Change in weight			
kg	−2.01 (4.33)	−0.44 (4.00)	<.001
Percent reduction in initial weight	−2.87 (6.10)	−0.52 (5.46)	<.001
Change in BMI, kg/m^2	−0.79 (1.69)	−0.17 (1.55)	<.001
Change in waist circumference, cm	−3.10 (6.02)	−0.71 (5.82)	<.001
Change in body fat, %	−1.20 (2.76)	−0.13 (2.22)	<.001
Change in energy intakes, kcal/d[a]	−76.9 (515)	5.62 (561)	.12
Change in leisure time activity, min/d	2.38 (9.80)	1.11 (12.0)	.25
Interventional goals, %			
Weight reduction >5% in initial weight	30.2	17.5	.003
Fat intake <30% of energy intake[a]	37.6	38.2	.89
Carbohydrate intake >55% of energy intake[a]	45.0	49.8	.33
Fibre intake >20 g/d[a]	4.2	1.8	.16
Exercise >30 min/d	16.4	15.7	.84

Abbreviation: BMI, body mass index. Data are changes in mean (SD), and percentage (%) unless otherwise indicated.

[a] Dietary intakes are assessed by 3-d 24-h food records.

TABLE 3 Changes in body weight, energy intake and leisure time physical activity from baseline to the end of months 1, 3, 6 and 9 in the intervention group among participants who completed study visits

	Month 1	Month 3	Month 6	Month 9
Numbers of participants	423	434	490	371
Change in weight				
kg	−0.41 (1.69)	−0.68 (2.04)	−0.74 (2.54)	−1.00 (3.11)
Percent reduction in initial weight	−0.59 (2.66)	−1.01 (3.22)	−1.07 (3.91)	−1.46 (4.66)
Change in energy intakes, kcal/d[a]	−57.7 (452)	−89.2 (461)	−85.9 (478)	−63.4 (491)
Change in leisure time activity, min/d	0.42 (8.01)	1.07 (10.8)	1.45 (10.0)	2.32 (10.0)
Numbers of participants with baseline BMI <24 kg/m^2	229	247	280	206
Change in weight				
kg	−0.10 (1.41)	−0.24 (1.69)	−0.13 (1.82)	−0.19 (2.00)
Percent reduction in initial weight	−0.18 (2.57)	−0.44 (3.07)	−0.22 (3.28)	−0.32 (3.54)
Change in energy intakes, kcal/d[a]	−9.00 (393)	−33.3 (431)	−18.4 (442)	−9.50 (446)
Change in leisure time activity, min/d	0.50 (7.72)	0.02 (9.23)	0.67 (10.5)	1.76 (9.08)
Numbers of participants with baseline BMI ≥24 kg/m^2	194	187	210	165
Change in weight				
kg	−0.78 (1.91)	−1.25 (2.31)	−1.56 (3.08)	−2.01 (3.87)
Percent reduction in initial weight	−1.07 (2.69)	−1.76 (3.27)	−2.21 (4.38)	−2.88 (5.45)
Change in energy intakes, kcal/d[a]	−115 (508)	−163 (489)	−176 (510)	−131 (536)
Change in leisure time activity, min/d	0.32 (8.36)	2.46 (12.4)	2.48 (9.27)	3.01 (11.1)

Abbreviation: BMI, body mass index. Data are changes in mean (SD) unless otherwise indicated.

[a] Dietary intakes are assessed by 3-d 24-h food records.

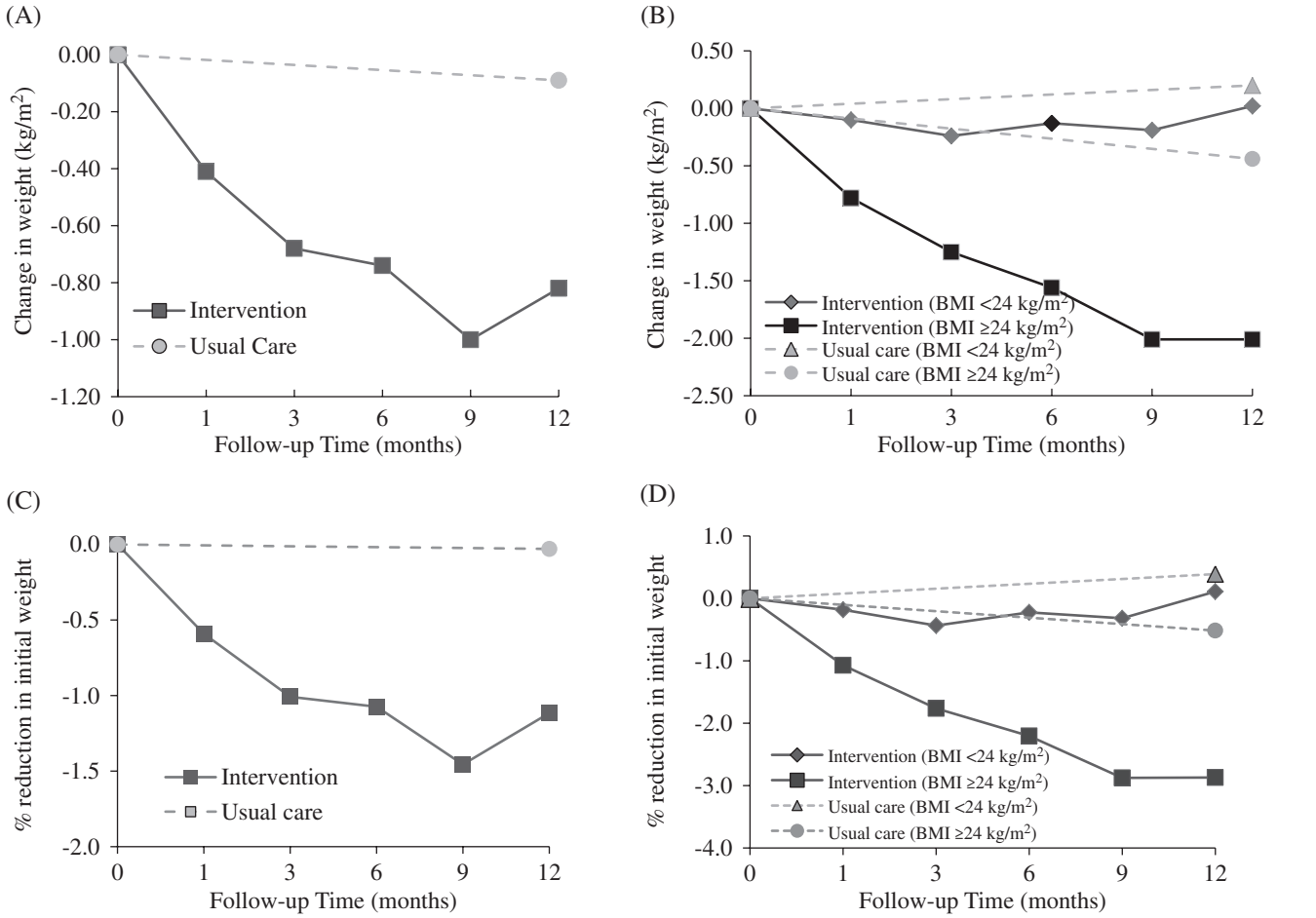

FIGURE 2 Changes in body weight and percentage reduction of initial weight from baseline to the end of month 1, 3, 6, 9 and 12 among participants who completed study visits

modestly reduced postpartum weight retention and increased vigorous-intensity physical activity during the first 12-month postpartum period.[26] It seemed that the reduction in postpartum weight retention might be explained by the significant increase in vigorous intensity activity among women in the intervention group because no differences were observed for changes in daily total energy intake.[26] One recent cohort study showed that 81% of women had higher body weight at 3 months postpartum compared with their body weight before pregnancy, and 74.4% of women lost weight from 3 to 12 months postpartum; this weight loss might be associated with changes in breastfeeding status and leisure time physical activity.[27] It has been shown that most women naturally lose weight throughout the breastfeeding process[28]; thus, an increase in physical activity and breastfeeding exclusively might help women diagnosed with GDM to manage their weight during the early postpartum period.

The present study found that lifestyle intervention led to a significant weight loss in women with GDM, and the effect was more pronounced in those who were overweight 1 to 5 years after delivery. All participants in the present study started the lifestyle intervention RCT at 1 to 5 years postpartum (mean 27.1 months). Almost all of them stopped breastfeeding before the study began and the mean duration of breastfeeding was 10.4 months, therefore, their energy intake levels and body weight were likely to have been stable before the baseline survey, with the exception of intentional active weight loss efforts. Unlike the few previous RCTs,[25,26] we found that significant reduction in daily energy intake (115-176 kcal/d) within the first year of the RCT among overweight women and an increase in leisure time physical activity (0.42-2.32 min/d) among all participants could have resulted in the significantly greater weight loss among women with GDM in the intervention group compared with those in the control group. It seems that the significant reduction in daily energy intake at months 3 to 9 (131-176 kcal/d) contributed to a greater weight loss among overweight women with GDM in the intervention group.

An important strength of the present study is that it is the largest RCT to date on type 2 diabetes prevention through diet and lifestyle modifications in women with GDM at 1 to 5 years postpartum. A limitation of the study is the 79% retention rate during the follow-up; however, the retention rate of the present RCT is similar to that of another large weight loss RCT, the POUNDS Lost study (80%),[29] and higher than those of other large GDM intervention RCTs, such as the Gestational Diabetes' Effects on Moms study (67.3%).[26] In addition, an intention-to-treat analysis that included all randomized participants was conducted in the present study.

The 1-year lifestyle intervention led to significant weight loss after delivery in women who had been diagnosed with GDM 1 to 5 years earlier. The efficacy was more pronounced in those who were overweight at 1 to 5 years after delivery. Our findings indicate that lifestyle intervention is feasible and effective in women with GDM soon after delivery.

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Conflict of interest

None declared.

Author contributions

GH has full access to all of the data in this study. HL, HT, LQ, JT, XY, ZY, and GH were responsible for the study design and implementation. HL, LW, SZ, JL, NL, and WL collected and extracted data. WL, JW and GH did the statistical analysis. HL and GH wrote the first manuscript. All authors reviewed and approved the final manuscript.

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SUPPORTING INFORMATION

Additional Supporting Information may be found online in the supporting information tab for this article.

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